TSCA Terminology Background

During discussions of the Agency's activities with respect to PFOA, the following terms relating to the Toxic Substances Control Act and to certain Agency procedures may be used.

Section 4(f) of TSCA:

Section 4(f) directs EPA to conduct an expedited review of a chemical under certain circumstances. This provision is only triggered by information related to three specific toxic effects: cancer, gene mutations, or birth defects. If the Agency determines that it has information that indicates that there may be a reasonable basis to conclude that a chemical presents a significant risk of serious or widespread harm from one of those three effects, EPA must conduct an expedited review of the chemical in no more than 270 days. At the end of the review, EPA must either determine that the benefits associated with the manufacture and use of the chemical exceed the risks, or it must initiate appropriate regulatory action to prevent or reduce the risks so that the benefits associated with the manufacture and use of the chemical will exceed the risks.

Section 8(e) of TSCA:

Section 8(e) requires manufacturers, processors, and distributors of chemicals to submit to EPA "adverse effects" information they have about the chemicals they manufacture, process, or distribute. Specifically, it requires that manufacturers, processors, and distributors provide to the Agency information that they obtain about a chemical if the information supports the conclusion that the chemical presents a substantial risk of injury to health or the environment.

Enforceable Consent Agreement (ECA):

An enforceable consent agreement (ECA) is a publicly negotiated agreement among EPA, industry, and interested parties that requires certain signing parties to generate data and submit those data to EPA on a specified schedule. ECAs can be a much quicker way to obtain data than pursuing a test rule under section 4 of the Toxic Substances Control Act. ECAs are enforceable, meaning that EPA can compel the submission of information agreed to under the ECA. Because they are negotiated in public, all parties who are interested in the data have the opportunity to participate.

Letter of Intent (LOI):

A Letter of Intent is a unilateral statement by a company, group, or individual describing activities they are undertaking, and making voluntary commitments to perform those activities as described. Because the commitments in such a letter are voluntary, the letters are not binding or enforceable.

Section 5 of TSCA:

Section 5 of TSCA requires manufacturers of new chemicals, and manufacturers and processors of certain existing chemicals, to notify EPA before any manufacture or processing takes place. Insofar as it applies to existing chemicals, Section 5 allows EPA to issue a regulation designating uses of existing chemicals as "significant new uses" (based upon, among other things, a consideration of the projected volume of manufacturing and processing of the chemical and the extent to which the new use changes the nature or magnitude of exposure to the chemical). If the Agency issues such a regulation (called a "significant new use rule" or "SNUR"), a manufacturer or processor must notify the Agency 90 days before commencing manufacture or processing of the chemical for the significant new use. If EPA determines during the 90-day review period that there is a significant question as to whether the new use should be allowed, EPA may take steps to prohibit or otherwise regulate the new use. Specifically, if EPA concludes that it lacks sufficient information to make a reasoned evaluation of the health and environmental effects associated with the use and either (1) the use may present an unreasonable risk of injury to health or the environment, or (2) the use will result in significant or substantial exposures to the chemical, EPA may establish appropriate regulatory limitations until data are submitted to allow the Agency to determine whether the new use meets the risk-benefit standard of TSCA.

Section 6 of TSCA:

Section 6 of TSCA allows EPA to issue a regulation that prohibits or otherwise regulates the manufacturing, processing, distribution, use, and/or disposal of a chemical if there is a reasonable basis to conclude that the rule will prevent an "unreasonable risk" of injury to health or the environment. A risk is "unreasonable" if the risks associated with the activity exceed the benefits associated with that activity. In regulating a chemical, EPA must select the "least burdensome" regulatory option that will adequately protect against the unreasonable risk. The range of options that can be considered is very broad, extending from warning statements to use restrictions to bans on all manufacture of a chemical.

Section 7 of TSCA:

Section 7 of TSCA allows EPA to take regulatory action quicker than can be obtained under section 6 (which requires extensive rulemaking before regulatory action becomes effective) if a chemical presents an "imminent hazard" (defined as an unreasonable risk of serious or widespread injury to health or the environment with the injury likely to result before a regulation could be promulgated under section 6). In order to regulate an imminent hazard, EPA must file an action in a federal district court; if the court agrees with that a situation presents an imminent hazard, it may order whatever relief it determines appropriate.